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EXAMINER

HEWITT, JAMES M

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3679

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/773,697

Applicant(s)

HESSEL ET AL.

Examiner

James M. Hewitt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 5,6,9 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,7,15-19,24-39 and 41-45 is/are rejected.
- 7) ☒ Claim(s) 8,11-14,20-23 and 40 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 April 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/2/07 has been entered.

Election/Restrictions

This application contains claims 5-6 and 9-10 drawn to an invention nonelected with traverse in the reply filed 11/3/05. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Drawings

The replacement drawing sheet was received on 4/2/07 and is acceptable.

Claim Objections

Claims 27-28 and 36-45 are objected to because of the following informalities:

In claim 27, it is unclear as to how the pouch relates to the second device. Aren't they one and the same?

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In claim 36, it is unclear as to how the pouch relates to the second device. Aren't they one and the same?

In claim 39, line 3, "the first device" lacks proper antecedent basis.

In claim 39, line 3, "the second device" lacks proper antecedent basis.

In claim 40, line 3, "the first device" lacks proper antecedent basis.

In claim 40, line 3, "the second device" lacks proper antecedent basis.

In claim 41, line 3, "the first device" lacks proper antecedent basis.

In claim 41, line 3, "the second device" lacks proper antecedent basis.

In claim 42, line 3, "the first device" lacks proper antecedent basis.

In claim 42, line 3, "the second device" lacks proper antecedent basis.

In claim 43, line 3, "the first device" lacks proper antecedent basis.

In claim 43, line 3, "the second device" lacks proper antecedent basis.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 7, 15, 17, 19, 24-39 and 41-45 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,785,695 (Sato et al).

With respect to claim 1 and with particular reference to Figure 5, Sato et al disclose a coupling comprising: a first coupling part (on left side of Figure 5) on the first device and a second coupling part on the second device, the second device detachably coupling to the first device, with the first coupling part having a circumferential coupling groove (17) defined by a radial interior and exterior walls and ending in a free end face facing in the opposite direction of the first device, and the second coupling part including first and second discs (7, 19) each having an aperture, wherein at least a portion of the first disc overlaps at least a portion of the second disc (in the radial direction); and first and second coupling collars (inner collar of first disc and outer collar of second disc) designed around the apertures of the first and second discs, respectively, and extending mainly in a cross direction of each respective disc, wherein the second coupling collar extends through the aperture of the first disc in the same direction as the first coupling collar, and the two coupling collars of the second coupling part extend into and engage the circumferential coupling groove of the first coupling part.

With respect to claim 2, wherein the radial exterior wall of the coupling groove includes a circumferential projection (bulb) facing radially inwards and defining an offset.

With respect to claim 3, wherein at least a portion of the free end face of the coupling groove abuts closely against the first disc when the devices are operably connected to each other.

With respect to claim 4, wherein the radial exterior wall of the coupling groove is longer than the radial interior wall of the coupling groove when viewed in cross section.

With respect to claim 7, wherein the first and second coupling collars are arranged to be pressed together between the radial interior wall and exterior wall of the first coupling part when the devices are operably coupled.

With respect to claim 15, wherein the first disc has a greater diameter than the second disc.

With respect to claim 17, wherein at least the second disc is reinforced with at least one circumferential rib (inner collar of second disc).

With respect to claim 19, further comprising locking means (outer collar of first disc) for locking the first and second discs together when the devices are operably coupled together.

With respect to claim 24, wherein the first disc has a first section (portion of pouch 10) extending radially outwards from its aperture in a direction mainly perpendicular to the axis, and a conic section (portion of pouch 10, see Fig. 1b) extending radially outwards of and continuous with the first section.

With respect to claim 25, wherein the second disc (including pouch 15) extends conically outwards from the aperture of the second disc (see Fig. 1b).

With respect to claim 26, wherein the first coupling part is an implant for implantation around a stoma of an animal or human body.

With respect to claim 27, wherein the second coupling part is placed inside a pouch (10) for coupling with the implant with the coupling collars extending out through an aperture in the pouch.

With respect to claim 28, wherein an inside of an edge section along the aperture of the pouch is closely joined with an outer side of a radial first section of the first disc.

With respect to claim 29, Sato et al disclose a method for application of a coupling according to claim 1, comprising joining the two discs of the second coupling part, placing the second coupling part is placed inside the second device, and joining the inside of an area around an aperture of the second device with and fastened to the first disc with the coupling collars extending out through the aperture of the second device.

With respect to claim 30, further comprising pushing the two coupling collars of the second coupling part together are pushed into the coupling groove of the first coupling part.

With respect to claim 31, placing the radial exterior wall of the first coupling part in a guide groove in the first disc of the second coupling part while the second coupling part is in an opened position, and thereafter positioning the second coupling part in a closed position, wherein the radial exterior wall forms the outer definition of the coupling groove.

With respect to claim 32, which further comprises uncoupling the parts by releasing an engagement between the coupling parts by manipulation of the first disc.

With respect to claim 33, which further comprises releasing the engagement between the two coupling parts by distally displacing the first disc.

With respect to claim 34, which further comprises releasing the engagement between the two coupling parts by affecting the first disc with radially opposite compressive forces in peripheral areas.

With respect to claim 35, wherein the second device is an ostomy pouch (10).

With respect to claim 36, Sato et al discloses a method for application of the coupling according to claim 1, comprising implanting the first coupling part around a stoma, wherein the first coupling part in the form of an annular implant having a projecting section with the coupling groove, and coupling an ostomy pouch (10) to the implant by pushing the two coupling collars of the second coupling part into the coupling groove of the first coupling part.

With respect to claim 37, which further comprises releasing an engagement between the two coupling parts is manipulation of the first disc.

With respect to claim 38, which further comprises releasing an engagement between the two coupling parts manipulation of a locking means (collars and groove) for disengaging the first and the second disc.

With respect to claim 39 and with particular reference to Figure 5, Sato et al disclose a coupling comprising: a first coupling part (on left side of Figure 5) on the first device and a second coupling part on the second device, the second device detachably coupling to the first device, with the first coupling part having a circumferential coupling groove (17) defined by a radial interior and exterior walls and ending in a free end face facing in the opposite direction of the first device, and the second coupling part including first and second discs (7, 19) each having an aperture; a pouch (15), wherein at least a

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portion of the pouch is positioned between the first and second disc; and first and second coupling collars (inner collar of first disc and outer collar of second disc) designed around the apertures of the first and second discs, respectively, and extending mainly in a cross direction of each respective disc, wherein the second coupling collar extends through the aperture of the first disc in the same direction as the first coupling collar, and the two coupling collars of the second coupling part extend into and engage the circumferential coupling groove of the first coupling part.

With respect to claim 41 and with particular reference to Figure 5, Sato et al disclose a coupling comprising: a first coupling part (on left side of Figure 5) on the first device and a second coupling part on the second device, the second device detachably coupling to the first device, with the first coupling part having a circumferential coupling groove (17) defined by a radial interior and exterior walls and ending in a free end face facing in the opposite direction of the first device, and the second coupling part including first and second discs (7, 19) each having an aperture; locking means (outer collar of first disc) for locking the first and second discs together; and first and second coupling collars (inner collar of first disc and outer collar of second disc) designed around the apertures of the first and second discs, respectively, and extending mainly in a cross direction of each respective disc, wherein the second coupling collar extends through the aperture of the first disc in the same direction as the first coupling collar, and the two coupling collars of the second coupling part extend into and engage the circumferential coupling groove of the first coupling part.

With respect to claim 42 and with particular reference to Figure 5, Sato et al disclose a coupling comprising: a first coupling part (on left side of Figure 5) on the first device and a second coupling part on the second device, the second device detachably coupling to the first device, with the first coupling part having a circumferential coupling groove (17) defined by radial interior and exterior walls and ending in a free end face facing in the opposite direction of the first device, and the second coupling part including first and second discs (7, 19) each having an aperture, wherein the second disc (including pouch 15) extends conically outwards from its aperture (see Fig. 1b); and first and second coupling collars (inner collar of first disc and outer collar of second disc) designed around the apertures of the first and second discs, respectively, and extending mainly in a cross direction of each respective disc, wherein the second coupling collar extends through the aperture of the first disc in the same direction as the first coupling collar, and the two coupling collars of the second coupling part extend into and engage the circumferential coupling groove of the first coupling part.

With respect to claim 43 and with particular reference to Figure 5, Sato et al disclose a coupling comprising: a first coupling part (on left side of Figure 5) on the first device and a second coupling part on the second device, the second device detachably coupling to the first device, with the first coupling part having a circumferential coupling groove (17) defined by a radial interior and exterior walls and ending in a free end face facing in the opposite direction of the first device, and the second coupling part including first and second discs (7, 19) each having an aperture; and first and second coupling collars (inner collar of first disc and outer collar of second disc) designed around the

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apertures of the first and second discs, respectively, and extending mainly in a cross direction of each respective disc; wherein the first and second disc each have portions (portion of pouch 10 and portion of pouch 15) which extend radially outward from the first and second coupling collars, respectively; wherein the second coupling collar extends through the aperture of the first disc in the same direction as the first coupling collar, and the two coupling collars of the second coupling part extend into and engage the circumferential coupling groove of the first coupling part.

With respect to claim 44, wherein the first disc has an axis, a first section (portion of pouch 10) extending radially outwards from its aperture in a direction mainly perpendicular to axis, and a conic section (portion of pouch 10, see Fig. 1b) extending radially outwards of and continuous with the first section.

With respect to claim 45, wherein the second disc (including pouch 15) extends conically outwards from the aperture of the second disc (see Fig. 1b).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,785,695 (Sato et al).

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Regarding claim 16, Sato et al fail to teach that the second disc is more rigid than the first disc. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the second disc of a material more rigid than the first since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

Regarding claim 18, Sato et al fail to teach that the first disc is made of a transparent material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the first disc of a transparent material since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

Allowable Subject Matter

Claims 8, 11-14 and 20-23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 40 is allowed.

Response to Arguments

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Applicant's arguments filed 4/2/07 have been fully considered but they are not persuasive.

Regarding the rejection of claim 1 under 35 U.S.C. 102(b) by Sato et al, Applicant asserts "Specifically, there is no disclosure, teaching or suggestion in the Sato '695 patent of a portion of a first disc overlapping a portion of a second disc." Examiner disagrees. In the radial direction, or from a side or lateral view, a portion of Sato's first disc (7) overlaps Sato's second disc (19). Refer to Fig. 1b and Fig. 5, and col. 7, ll. 3-8, col. 8, line 55 – col. 9, line 4.

Regarding the rejection of claims 39 and 43 under 35 U.S.C. 102(b) by Sato et al, Applicant argues that Sato et al fail to disclose the limitation "wherein the second coupling collar extends through the aperture of the first disc in the same direction as the first coupling collar." Examiner disagrees. As evidenced in Fig. 5, Sato's second coupling collar (outer collar of second disc 19) extends through the aperture of the first disc (7) in the same direction as the first coupling collar (inner collar of first disc 7). Interpreted another way, when Sato's device is in the assembled state, the second coupling collar extends (in a radial direction) through the aperture of the first disc in the same direction as the first coupling collar.

Conclusion

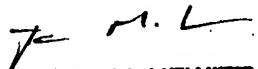
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to James M. Hewitt whose telephone number is 571-272-7084.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Stodola can be reached on 571-272-7087. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JMH
6/13/07


JAMES M. HEWITT
PRIMARY EXAMINER